REMARKS

Attached hereto as **Exhibit A** are substitute pages containing the amendments to the specification and claims requested herein. 37 C.F.R. § 1.121 (effective November 7, 2000).

Entry of the present amendments and new claims increases by three (3) the total number of independent claims four to seven because of new independent claims 26 to 28 (in addition to original independent claims 1, 11, 16 and 22). The total number of claims (independent and dependent) increases by four (4) because of the addition of new claims 26 to 29. Accordingly, an additional claims fee of ONE HUNDRED and FIFTY-SIX DOLLARS ($156.00) for a small entity is believed to be required, and a check in this amount is enclosed.

No fees, other than the enclosed, are believed to be required for entry and consideration of the present PRELIMINARY AMENDMENT. However, should any additional fees be deemed necessary, please charge Deposit Account No. 08-2776 of the below-identified firm as required.

If the Examiner has any questions about the above, Applicant's Attorney Gordon F. Belcher is requested to be contacted at the telephone number below. Additionally, please address all correspondence to the below-identified firm at the address below.

Please return the enclosed self-addressed postcard stamped by the PTO to indicate timely receipt of the enclosed.

Respectfully submitted,

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Certificate of Mailing Under 37 C.F.R. § 1.8

I hereby certify that this PRELIMINARY AMENDMENT, and every attachment and enclosure referred to therein, including **Exhibit A** is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to:

Commissioner for Patents
Washington, D.C. 20231

on November 22, 2000
(Date of Deposit)

Rita Akgün
(Name of person making deposit)

(Signature)

verify screw length) and applies to circumstances where the instrument or implant is to be advanced "end on" the target tissue and parallel to the direction of the fluoroscopic or roentgenographic beam. In instances where this is not the case, *e.g.*, when the start point for an intramedullary nailing on the skin needs to be determined, knowing that this position on the skin must be collinear with the proximal femoral shaft, the assessment of colinearity can be accomplished by applying the surgical targeting grid of the present invention so that it is collinear with the proximal femur on the lateral aspect (this may require C-arm fluoroscopic X-ray check during the act of grid placement, with extension of the placement cephalad as far as the buttock) as well placement of a second grid on the anterior aspect with extension cephalad as far as the buttock at which point it overlaps the first surgical targeting system. By noting which grid row overlies the proximal femoral canal on the anteroposterior projection and also noting which grid row from the second surgical targeting system overlies the proximal femoral canal on the lateral projection, the start point on the skin is given by the intersection of these two rows on the surface of the buttock area. This is of special importance in percutaneous intramedullary nailing procedures, where the selection of an incision point which is not collinear with the proximal femur may cause tenting of a large cuff of soft tissue during the procedure and may necessitate extension of a small incision. Finding this point on the skin might otherwise entail multiple fluoroscopic X-ray views, each of which impart radiation exposure to the patient

as well as the surgeon and other

operating room personnel. An additional point is that accurate location of this point permits a small skin incision and this, with healing becomes a small scar which, if later extraction of the device is opted for, facilitates the accomplishment of the procedure, again, as a percutaneous one (with a limited incision whose locus is given by the existing scar).

Another example of the utility of the system of the present invention is provided by the procedure of reamed femoral intramedullary nailing. When the currently commonly utilized process (using an overlying radiopaque object to find a locus on the skin as described above) is used to monitor the passage of a surgical instrument down a surgical corridor, multiple additional fluoroscopic views may be needed. An example of this would be passage of a guidewire down an intramedullary canal for a fracture of the femur. Knowing which direction to point the angled tip of the guide wire entails knowing which direction the fragment on the other side of the fracture is displaced. Additional spot fluoroscopic views of the fracture with an overlying radiopague object (such as a hemostat clamp, such as for clamping a blood vessel) gives the needed answer and prompts the surgeon to rotate the guidewire so that its tip is toward the intramedullary canal on the displaced fragment before advancing the wire down the fragment's canal. With a surgical targeting device of the present invention in place, obtaining additional fluoroscopic X-rays for this purpose are unnecessary. The added advantageous factor is that the surgeon need not place his hand near the radiation beam with the

surgical instrument (this is an occupational hazzard for many surgeons).

Additionally, minor directional adjustments in the passage of a radiopaque instrument or implant in the body can be subject to less guesswork because both the coordinates on the fluoroscopic screen and those directly readable on the patient can be correlated. "Guesswork" however may prompt the operator to take more fluoroscopic X-rays or may result in the need for several passes through the patient's tissues with the instrument or implant before the correct corridor is gotten. Having an in place targeting system of the present invention, therefore, may provide the surgeon with a series of constant reference points throughout the entirety of the procedure. Having these may facilitate the accuracy and speed of the procedure and diminish the potential hazzard to the patient (additional radiation exposure and damage to tissues from inaccurate passage of instruments or implants under fluoroscopic control) as well as to the surgeon and the operating room personnel (radiation exposure).

U.S. Patent 5,702,128 discloses a radiographic marker system and method of making it. The entire disclosure of U.S. Patent 5,702,128 is hereby incorporated by reference herein. U.S. Patent 5,052,035 (referred to herein as the "'035 patent") discloses image location marking devices for radiographs, a method of marking and methods of use. The entire disclosure of U.S. Patent 5,052,035 is hereby incorporated by reference herein.

Instead of a lead marker, the device disclosed in the '035 patent produces multiple parallel lines on an X-ray film bearing a radiographic image of a patient's

impervious to liquid strike through or fluid flow through it is an important feature of this device of the present invention. On the other hand, a drape that allows fluid transfer, and thus bacterial transfer, compromises the sterile field. This, in turn, potentially increases the risk of wound infection. For surgical procedures of length, active antimicrobial on the skin in the operative field is a desirable feature. Thus, the inclusion of an antiseptic coating on the drape of the present invention exposed to the skin provides an additional safeguard against infection.

Once a patient's skin has been prepped or prepared for surgery, the sterile Ioban® drape of the present invention is stretched over the area to be incised. The designed function of the Ioban® drape is to provide an added sterile and antiseptic protective barrier within the surgical field placed on the patient's skin and the adjacent operating environment. The Ioban® drape's adhesive properties are often used as a means of securing the sterile drapes or towels to the margins of the surgical field. This feature is an important one when the surgeon is planning a percutaneous procedure with fluoroscopic control, because securing the drapes and towels to the margins of the field in the customary fashion with the use of radiopaque towel clips might otherwise interfere with the ability of the operator to visualize the target or targeted area within the body on the fluoroscopic image.

Summary of the Invention

This invention consists of a thin radiolucent sheet of translucent or transparent material upon which is located a series of radiographically dense numbered and/or lettered lines or otherwise distinguishable markings. One possibility is to dispose a set of lines at regular intervals and a second set of similarly disposed radiographically dense numbered and/or lettered lines are at right angles to the first, so as to form a series of small distinguishable quadrants or intersecting points, *i.e.*, a grid. Many patterns for the design of these patterns are possible, depending on the particular application. These lines as well as their labels are readily seen directly when applied to the patient's body and are also clearly visible when the area to which they are applied is imaged with fluoroscopic x-rays.

Other features of the invention are that the sheet is sterile and the side that is applied to the patient's skin has a uniform distribution of adhesive (although the amount of adhesive is contingent on the specific application). Additionally, the side of the drape applied to the patient's skin also may have a topical antiseptic. The sheet comes with a second layer on the adhesive side, which readily peels off and allows for application of the adherent portion of the targeting grid sheet to the skin of the patient.

Application of the surgical targeting grid to the surface of the body permits a more accurate localization of radiodense structures or bodies within

the zone of targeting by fluoroscopic or radiographic imaging. A surgical instrument or implant can be directed to the target tissue or target object by taking advantage of the surgical targeting system in several ways. For example, once the grid marking or coordinate overlying the target on the fluoroscopic image is located on the surface of the body, that becomes the start point for the passage of the instrument/implant to the target, with care to remain co-linear with the fluoroscopic/X-ray incident beam. Additionally, by disposing the surgical targeting sheet around the portion of the body to be imaged in a hemicircumferential or circumferential manner, two grids (on opposite sides of the body or body part or in different planes from each other *e.g.*, the lateral side and anterior surface of the thorax) can be simultaneously utilized to locate a lesion or a structure. Advantage can thus be taken of the parallax effect of two grids, with one being disposed on the near (to the receiver tube of fluoroscope ((image intensifier)) or developing cassette of the X-ray) body surface and one being disposed on the far or opposite body surface. Determination of depth and relative angle of passage can be ascertained by a grid and corresponding fluoroscopic image or X-ray of the target or passing instrument or implant at right angles to the parallel near and far grids. Overlapping near and far (located on opposite sides of the body or limb) grids can also be utilized in enabling the operator to exactly duplicate a fluoroscopic/X-ray view that was gotten earlier in a procedure. This can occur by making note of overlapping near and far grid coordinates on the view

of interest gotten prior. Duplicating this angle

Fig. 22 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of Fig. 18;

Fig. 23 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of Fig. 19;

Fig. 24 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of Fig. 20;

Fig. 25 is a C-arm fluoroscopic view of the distal femur from the lateral (or medial) aspect with the overlapping surgical targeting system of Fig. 23, targeting of the holes in the distal portion of a femoral intramedullary nail being facilitated by the near and far grid coordinates in the target nail hole such that with the grid properly positioned, these coordinates are directly read on the skin surface;

Fig. 26 is a perspective view of an alternative embodiment of the surgical targeting system of Fig. 1 applied to a digit (finger depicted), the rolled closed tube being capable of being unrolled from the tip of the digit;

Fig. 27 is a perspective view of the surgical targeting system of Fig. 26, the rolled closed tube being unrolled further toward the base of the digit;

Fig. 28 is a view of a radiographic image of the digit and overlying surgical targeting system of Fig. 27 illustrating the skeletal elements of the digit;

Fig. 29 is a perspective view of an alternative embodiment of the surgical targeting system of Fig. 26;

Fig. 30 is a perspective view of the surgical targeting system of Fig. 29 illustrating the rolled closed tube unrolled further toward the base of the digit;

Fig. 31 is a perspective view of an alternative embodiment of the surgical targeting system of Fig. 1 for application to a human breast, the surgical targeting system including a cone-shaped drape with a cutout having an aperture in the center corresponding to the nipple of the breast;

Fig. 32 is an anterior view of the surgical targeting system of Fig. 31 showing the surgical grid as a polar coordinate system;

Fig. 33 is a superior view of a patient to whom the surgical targeting system of Fig. 31 is applied, the patient undergoing mammographic imaging where the emitter tube is medial and the receiving tube is lateral;

Fig. 34 is a view of the fluoroscopic mammographic image obtained from the apparatus depicted in Fig. 33 showing a lesion located cephalad, in line with the specific grid markings illustrated;

Fig. 35 is a lateral view of a patient to whom the surgical targeting system of Fig. 31 is applied, the patient undergoing mammographic imaging where the emitter tube is cephalad (above) and the receiver tube is caudad (below); and

Fig. 36 is a view of the fluoroscopic mammographic image obtained from the apparatus depicted in Fig. 35 showing a lesion located laterally, in line with the specific grid markings illustrated.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Detailed Description of the Invention

The surgical targeting system of the present invention combines the advantages of both a marking device for radiograph and a plastic adhesive wound drape such as the Ioban® drape. The device is composed of a thin, sterile flexible, transparent or translucent sheet which has varying amounts of uniformly distributed adhesive and topical antiseptic such as iodophor on the side which is to be applied to the patient's skin. To facilitate packaging and application to the patient, a removable and disposable layer on the adherent side (which is pealed off when applied) may be incorporated.

Additionally, a series of easily distinguishable radiopaque lines are incorporated either on or within the layers of the drape. One method of distinguishing the radiopaque lines is their being disposed in a pattern and labeled with radiopaque material. The pattern of the radiopaque elements and the labels/coordinates are easily visible on the drape as well as on a radiographic/fluoroscopic image of the drape. The radiopaque medium forms a distinctive pattern of lines on the drape, which allows for easy localization of the pathology or the targeting point within the radiographic image. The radiopaque medium may be, but is not limited to, fine steel wire (having a diameter of 0.003 inches) or a slurry of some radiopaque material such as barium or calcium sulfate.

The material of the lines is radiopaque while the surgical drape material is radiolucent, which means only the lines of the drape and their corresponding

compromised.

Figs. 6, 7 and 8 illustrate an embodiment of the surgical targeting system 29 in which the surgical targeting system 1 is applied to anterior, lateral and posterior portions of the outer surface 34 of the chest or torso 31 of a body. The surgical targeting system 29 includes a drape 36 (corresponding to the drape 9), outer and inner surfaces 39, 41 (corresponding to the outer and inner surfaces 11, 14), and longitudinal and lateral edges 44, 46 (corresponding to the longitudinal and lateral edges 16, 19). The surgical targeting system 29 also includes indicia 56 (corresponding to the indicia 21) and adhesive 59 (corresponding to the adhesive 24). The drape 36, as applied to the torso 31, has anterior, lateral and posterior portions 49, 51, 54, as illustrated in Figs. 6, 7 and 8.

An emitter 61, such as an X-ray tube, and a receiver 64, such as an image intensifier, arranged as shown in Figs. 9 and 11, may be employed to produce the images illustrated in Figs. 10 and 12, respectively. Figs. 10 and 12 include indicia images 65 (corresponding to the indicia 56), a lesion image 66, rib images 69 and a sternum image 71.

The anatomical terms "superior" a and "inferior" b, with respect to the human body, refer to locations nearer to the head and to the feet of the body, respectively, relative to other locations. The anatomical terms "anterior" c and "posterior" d, with respect to the human body, refer to locations nearer

right drape 196 has an inner surface 201 which, like the inner surface 14 of the drape 9, may be coated with an antiseptic. The right drape 196 also has an outer surface 199.

The right drape 196 is conical and has a radial cutout 206. The cutout 206 has a base 209 which coincides with a peripheral edge 204 of the drape, and a central aperture 211.

The surgical targeting system 189 has indicia 214 similar to the indicia 21. The indicia 214 are preferably a system of polar coordinates having a center coinciding with the apex of the right drape 196, as shown in Fig. 32. The indicia 214 of the polar coordinate system shown of Fig. 32 may include a radiopaque medium forming two sets of thin lines. The first set of lines radiates from a common center. The second set of lines forms concentric circles whose center is coincident with the intersection of the radial lines. The spacing between the radial lines and concentric circles varies from drape to drape depending on the specific application of the drape as well as the size of the tissue to be targeted. Depending on the material chosen to make the lines, the lines may also have to be broken at the intersections, as described herein above for the rectangular coordinate system, to allow for optimal flexibility of the system. Alternatively, if added stiffness is desirable and a specific tissue is hypermobile and therefore less amenable to targeting, a "closed" wire system with thicker and stiffer wires may be preferred. Each line or intersection is also

Localization of tracts (e.g, sinus tract infection);

Positioning of ultrasonic or magnetic field stimulation in relation to bone/soft tissue fixation;

Wire and pin placements for cannulated screw fixation and accurate bone anchoring;

Manipulation/removal/repositioning of existing implants;

As an aid to the accomplishment of percutaneous procedures;

As a means of cross checking computer guided or computer assisted surgery Intracranial targeting;

As an aid in biopsying/staging gastrointestinal/ urinary tract tumors (in combination with endoscopic findings-the surgical targeting grid can be used to locate the tip of the endoscope, and thereupon direct the tip of a laparoscope to visualize the outside wall of the viscus for the purpose of staging/biopsy);

As an aid in directing the placement of a mediastinal scope;

As an aid in determining the position of a bronchoscope; and

Placement of other implants or reservoirs.

Alternative embodiments of the invention are possible, in addition to integrating this grid system into a sterile drape. For example, other methods of surgical targeting may be employed by combining a sterile radiopaque grid with a removable glove or sock or a condom for the extremity, finger or other appendage. Such a device is stretchable with enough friction to minimize any shearing between it and the skin and may not require adhesive backing or perhaps

distinguishing radiopaque labels. Both the lines and the labels are easily readable both on fluoroscopic views as well as directly once the targeting systems have been applied to the surface of the body.

Simultaneous application of the drape (or separate drapes) to "near" and "far" body surfaces enables the surgeon to take advantage of parallax and utilize both surgical grids for precise direction of a surgical tool or implant such as a needle, drill, pin, rod, biopsy tool or trocar. Similarly, by locating two grids over the body area of interest at right angles to each other, one grid can be used to isolate a starting point and the second grid can be utilized with fluoroscopic views also at right angles to the overlying second grid to control the depth and angle of inclination of the inserted instrument or implant. This feature of parallax can also be utilized in the instance of overlapping (near and far) grids, disposed on opposite sides of the body or body part by assuring co-linearity of the target with far and near grid points. Subtle adjustments in the angle of the radiographic/fluoroscopic beam result in changes in the collinear near and far coordinates.

Once the desired coordinates for passage of the instrument or implant are known, several strategies incorporating the grid coordinates can then be used to assist targeting. One strategy for the accomplishment of this would entail a visible light beam projection from the middle of the C-arm fluoroscope from both the emitting and receiving elements, directed by the operator to the corresponding near and far target grid

provide access to the outer surface of the body; and

means for fixing said drape to the outer surface of the body, said drape and fixing means being sterile to provide a sterile field around the outer surface of the body accessed by puncturing of said drape.

12. The sterile field system of claim 11 wherein said drape comprises plastic impregnated with iodophor.

13. The sterile field system of claim 11 wherein said fixing means comprises adhesive applied to the surface of said drape which contacts the outer surface of the body.

14. The sterile field system of claim 11 wherein said fixing means comprises forming said drape of expandable material and sizing said drape to have an internal volume which is less than the volume of the elongate body enabling said drape to be shrink-fitted onto the body.

15. The sterile field system of claim 11 wherein said drape is transparent to imaging radiation,

said sterile field system further comprising an indicia affixed to a portion of said drape, said indicia being opaque to the imaging radiation such that a radiographic image of the body resulting from passage of the image radiation through the body includes an indicia image corresponding to said indicia,

said fixing means fixing said indicia relative to the outer surface such that said indicia provides a reference on said body for correlating portions of the body to the radiographic image thereof.

16. A system for providing a sterile field around a conical body comprising:

a conical antimicrobial drape having sufficient flexibility to conform to at least a portion of an outer surface of the elongate body, said drape being puncturable to provide access to the outer surface of the body; and

means for fixing said drape to the outer surface of the body, said drape and fixing means being sterile to provide a sterile field around the outer surface of the body accessed by puncturing of said drape.

17. The sterile field system of claim 16 wherein said drape comprises plastic impregnated with iodophor.

18. The sterile field system of claim 16 wherein said fixing means comprises adhesive applied to the surface of said drape which contacts the outer surface of the body.

19. The sterile field system of claim 16 wherein said drape has a radial cutout having a base which coincides with a peripheral edge of said drape.

of the indicia intersected by an axis coinciding with a selected direction through the body,

wherein said locating step comprises locating the selected direction through the body by referencing the body relative to the portions of the indicia on the drape identified in said referencing of the radiographic image;

wherein said puncturing step comprises puncturing the drape to access the body adjacent to at least one of the portions of the indicia.

26. A method for correlating a selected portion of a body to a radiographic image of the body for treatment of the body, said method comprising the steps of:

applying a radio-transparent drape having radio-opaque indicia to the body;

fixing said drape and indicia to the body;

directing imaging radiation through said drape such that a radiographic image of said body and indicia is formed on a medium;

referencing on the radiographic image the selected portion of the body relative to the indicia;

locating the selected portion of the body by referencing the body relative to the indicia on the drape in a manner corresponding to said referencing of the radiographic image; and

surgically operating on the body contemporaneously with said locating step.

27. A method for correlating a selected portion of a body to a radiographic image of the body for treatment of the body, said method comprising the steps of:

applying a radio-transparent drape having radio-opaque indicia to the body such that portions of the drape define at least two surfaces inclined relative to one another;

fixing said drape and indicia to the body;

directing imaging radiation through said drape such that a radiographic image of said body and indicia is formed on a medium;

referencing on the radiographic image the selected portion of the body relative to the indicia, said referencing step further comprising identifying on the radiographic image respective indicia on the inclined two surfaces, said respective indicia being intersected by an axis coinciding with a selected direction through the body, said referencing step further comprising identifying on the radiographic image indicia on one of the inclined two surfaces coinciding with the depth of the selected direction relative to the other of the inclind two surfaces; and

locating the selected portion of the body by referencing the body relative to the indicia on the drape in a manner corresponding to said referencing step of the radiographic image, said locating step comprising identifying the selected direction and depth through the body by referencing the body relative to the indicia on the drape identified in said referencing step of the radiographic image.

28. A method for correlating the buttock with the femoral canal of the femur of a body, said method comprising the steps of:

applying a radio-transparent drape having at least two indicia each comprising a radio-opaque longitudinal axis to the leg of the body such that a first portion of the drape extends in an anterior-posterior plane relative to the body, said applying step further providing for a second portion of the drape to extend laterally relative to the body, said applying step providing further for each of the indicia to be contained in respective first and second portions of the drape, said applying step providing further for each of the indicia to be longitudinally and centrally aligned relative to the leg;

directing imaging radiation through said drape such that a radiographic image of said body and indicia is formed on a medium;

comparing, by viewing the radiographic image, the relative positions of each of the indicia relative to the longitudinal axis of the femoral canal;

translating the drape, as required, relative to the leg such that one of the indicias is contained in an anterior-posterior plane which coincides with the longitudinal axis of the femoral canal, and such that the other of the indicia is contained in a lateral plane which coincides with the longitudinal axis of the femoral canal; and

locating the intersection of the indicia on the buttock, the intersection of the indicia